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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,474	04/18/2001	Sau-Hung S. Leung	845.27,700	9942

29668 7590 06/25/2002

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/836,474

Applicant(s)

LEUNG ET AL.

Examiner

Todd D Ware

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Receipt of amendment filed 2-4-02 is acknowledged. Claim 18 has been amended as requested. Claims 18-30 are pending.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (5,948,430; hereafter '430) in combination with Nair et al (WO 98/11867; hereafter '867).

'430 teaches processes of making single layer, consumable water soluble films comprising a water soluble polymer and menthol that are substantially the same as those of the instant claims (abstract; C 2, L 31-64; C 3, L 32-40; examples). '430 does not teach that the total amount of the oils is at least about 5% or at least about 15% nor that the films have a moisture content of about 3 and 8%, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of oils for greater oral hygiene purposes and to adjust the moisture content accordingly to remove the solvents completely or almost completely from the film. '430 also does not teach the limitations of claim 25, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to omit heating the polymer/aqueous solution in the instance where the polymer dissolves, is

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soluble or becomes hydrated in the solution without heating to eliminate this step (MPEP 2144.04 II). '430 does not teach inclusion of another oil selected from thymol, eucalyptol, or methyl salicylate.

'867 teaches oral compositions comprising thymol, methyl salicylate, eucalyptol and menthol as flavoring and antibacterial agents. These oils may be used alone or in combination.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate the essential oils and cooling agents of '867 in the composition of '430 for flavor and antimicrobial purposes. Adjustment of the amounts of these agents in the composition is a manipulatable parameter that would be obvious to one skilled in the art to adjust in an effort to arrive at a desired taste of the composition.

3. Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horstman et al (5,629,003; hereafter '003) in combination with Nair et al (WO 98/11867; hereafter '867).

'003 teaches processes of making water soluble films that are substantially the same as those of the instant claims (abstract; C 3, L 56-61, 67; examples). '003 does not teach that the total amount of the oils is at least about 5% or at least about 15% nor that the films have a moisture content of about 3 and 8%, however it is submitted that it would have been obvious to one skilled in the art at the time of the invention to include greater amounts of oils for greater oral hygiene purposes and to adjust the moisture content accordingly to remove the solvents completely or almost completely from the film. '003 also does not teach the limitations of claim 25, however it is submitted that it

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would have been obvious to one skilled in the art at the time of the invention to omit heating the polymer/aqueous solution in the instance where the polymer dissolves, is soluble or becomes hydrated in the solution without heating to eliminate this step (MPEP 2144.04 II). '003 does not teach inclusion of another oil selected from thymol, eucalyptol, or methyl salicylate.

'867 teaches oral compositions comprising thymol, methyl salicylate, eucalyptol and menthol as flavoring and antibacterial agents. These oils may be used alone or in combination.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate the essential oils and cooling agents of '867 in the composition of '430 for flavor and antimicrobial purposes. Adjustment of the amounts of these agents in the composition is a manipulatable parameter that would be obvious to one skilled in the art to adjust in an effort to arrive at a desired taste of the composition.

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horstman et al (5,629,003; hereafter '003) in combination with Nair et al (WO 98/11867; hereafter '867) and further in combination with Hijiya et al (4,562,020; hereafter '020).

'003 and '867 are relied upon for all that they teach as stated previously. Neither of these references teaches the limitation where the polymer is pullulan.

'020 teaches strong, water soluble films comprising pullulan.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute the water soluble polymers of '430 with the motivation of imparting the strength properties of pullulan upon the composition.

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5. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe et al (5,948,430; hereafter '430) in combination with Nair et al (WO 98/11867; hereafter '867) and further in combination with Hijiya et al (4,562,020; hereafter '020).

'430 and '867 are relied upon for all that they teach as stated previously. Neither of these references teaches the limitation where the polymer is pullulan.

'020 teaches strong, water soluble films comprising pullulan.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to substitute the water soluble polymers of '430 with the motivation of imparting the strength properties of pullulan upon the composition.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 18-30 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

tw  
June 19, 2002